Claims 1-83, 87-89, 93 and 99-121 are presently pending in this application. Claims 84-86, 90-92 and 94-98 are cancelled herein without prejudice or disclaimer solely in the interest of advancing the prosecution of this application to allowance. Applicant reserves the right to file divisional applications directed to any cancelled subject matter.

TRAVERSAL OF RESTRICTION REQUIREMENT

Applicant respectfully traverses the restriction requirement. It is respectfully submitted that the Restriction Requirement as between groups I and III, and as between groups II and IV is improper.

Groups I and III

Applicant traverses the restriction requirement as between group I, which is directed to pharmaceutical compositions, kits and articles of manufacture containing formoterol, or a derivative thereof, and a steroidal anti-inflammatory agent, and group III, which is directed to pharmaceutical compositions, kits and articles of manufacture containing formoterol, or a derivative thereof, a steroidal anti-inflammatory agent, and at least one more active agent. Group III thus is directed to compositions which contain the compositions of group I plus at least one more active agent. Therefore, group III is related to group I as a combination/subcombination for which a showing of two-way distinctness is required.

Inventions that are related as a combination and subcombination are distinct and restriction may be proper **only if** it can be shown that the combination as claimed does not require the particulars of the subcombination as claimed for patentability **and** that the subcombination has utility by itself or in other combinations. See MPEP 808.05(c).

The subcombination, the compositions of group I, have use by themselves in the treatment of bronchoconstrictive disorders. Furthermore, if the compositions of group I are deemed free of the prior art, the compositions

of group III will necessarily be free of the prior art. Therefore, the compositions of group III and the compositions of group I are not distinct.

Also, if the claims are restricted into these two groups, applicant ultimately could be granted two patents, one that include claims encompassing pharmaceutical compositions containing formoterol, or a derivative thereof, and a steroidal anti-inflammatory agent, and another with claims directed to pharmaceutical compositions containing formoterol, or a derivative thereof, a steroidal anti-inflammatory agent, and at least one more active agent, that expire on different dates. If the claims to the combinations (group III) issued first, a later issuing patent encompassing the subcombination (group I) could not be held to constitute obvious-type double patenting over the earlier issuing patent. See MPEP 806, paragraph 3, which states:

> [w]here inventions are related as disclosed but are not distinct as claimed, restriction is never proper. Where restriction is required by the Office double patenting cannot be held, and thus, it is imperative the requirement should never be made where related inventions as claimed are not distinct.

See, also MPEP 804.01, which states:

> 35 U.S.C. 121 authorizes the Commissioner to restrict the claims in a patent application to a single invention when independent and distinct inventions are presented for examination. The third sentence of 35 U.S.C. 121 prohibits the use of a patent issuing on an application with respect to which a requirement for restriction has been made, or on an application filed as a result of such a requirement, as a reference against any divisional application, if the divisional application is filed before the issuance of the patent. The 35 U.S.C. 121 prohibition applies only where the Office has made a requirement for restriction. The prohibition does not apply where the divisional application was voluntarily filed by the applicant and not in response to an Office requirement for restriction. This apparent nullification of double patenting as a ground of rejection or invalidity in such cases imposes a heavy burden on the Office to guard against erroneous requirements for restrictions where the claims define essentially the same invention in different language and which, if acquiesced in, might result in the issuance of several patents for the same invention.

It is alleged that groups I and III are directed to unrelated subject matter since the subject matter of the groups allegedly have different modes of operation. Applicant respectfully disagrees. The compositions of both groups I and III are intended for the same use (*i.e.*, administration to a patient in need thereof for treatment, prevention, or amelioration of one or more symptoms of a bronchoconstrictive disorder). Therefore, the compositions of both groups I and III have the same mode of operation. As described in detail above, the compositions of groups I and III are related as a combination/subcombination for which a showing of two-way distinctness is required. The Office Action fails to provide such a showing.

Since such restriction is improper, reconsideration and withdrawal of the restriction requirement as between group I and group III is, therefore, respectfully requested.

Groups II and IV

Applicant traverses the restriction requirement as between group II, which is directed to methods of treatment, prevention, or amelioration of one or more symptoms of bronchoconstrictive disorders by administration of pharmaceutical compositions containing formoterol, or a derivative thereof, and a steroidal anti-inflammatory agent; and group IV, which is directed to methods of treatment, prevention, or amelioration of one or more symptoms of bronchoconstrictive disorders by administration of pharmaceutical compositions containing formoterol, or a derivative thereof, a steroidal anti-inflammatory agent, and at least one more active agent. Group IV thus is directed to methods using compositions which contain the compositions used in the methods of group II plus at least one more active agent. Therefore, group IV is related to group II as a combination/subcombination for which a showing of two-way distinctness is required.

Inventions that are related as a combination and subcombination are distinct and restriction may be proper **only if** it can be shown that the

combination as claimed does not require the particulars of the subcombination as claimed for patentability **and** that the subcombination has utility by itself or in other combinations. See MPEP 808.05(c).

The subcombination, the methods of group II, have use by themselves in the treatment, prevention, or amelioration of one or more symptoms of bronchoconstrictive disorders. Furthermore, if the methods of group II are deemed free of the prior art, the methods of group IV will necessarily be free of the prior art. Therefore, the methods of group IV and methods of group II are not distinct.

Also, if the claims are restricted into these two groups, applicant ultimately could be granted two patents, one that includes claims encompassing methods of treatment, prevention, or amelioration of one or more symptoms of bronchoconstrictive disorders by administration of pharmaceutical compositions containing formoterol, or a derivative thereof, and a steroidal anti-inflammatory agent; and another with claims directed to methods of treatment, prevention, or amelioration of one or more symptoms of bronchoconstrictive disorders by administration of pharmaceutical compositions containing formoterol, or a derivative thereof, a steroidal anti-inflammatory agent, and at least one more active agent, that expire on different dates. If the claims to the combinations (group IV) issued first, a later issuing patent encompassing the subcombination (group II) could not be held to constitute obvious-type double patenting over the earlier issuing patent. See MPEP 806, paragraph 3, which states:

> [w]here inventions are related as disclosed but are not distinct as claimed, restriction is never proper. Where restriction is required by the Office double patenting cannot be held, and thus, it is imperative the requirement should never be made where related inventions as claimed are not distinct.

See, also MPEP 804.01, which states:

> 35 U.S.C. 121 authorizes the Commissioner to restrict the claims in a patent application to a single invention when independent and distinct inventions are presented for examination. The third sentence of 35 U.S.C. 121 prohibits the use of a patent issuing on an application with respect to which a requirement for restriction has been made, or on an application filed as a result of such a requirement, as a reference against any divisional application, if the divisional application is filed before the issuance of the patent. The 35 U.S.C. 121 prohibition applies only where the Office has made a requirement for restriction. The prohibition does not apply where the divisional application was voluntarily filed by the applicant and not in response to an Office requirement for restriction. This apparent nullification of double patenting as a ground of rejection or invalidity in such cases imposes a heavy burden on the Office to guard against erroneous requirements for restrictions where the claims define essentially the same invention in different language and which, if acquiesced in, might result in the issuance of several patents for the same invention.

It is alleged that groups II and IV are directed to unrelated subject matter since the subject matter of the groups allegedly have different modes of operation. Applicant respectfully disagrees. The methods of both groups II and IV are directed to administration of a composition of group I or group III, respectively, for treatment, prevention, or amelioration of one or more symptoms of a bronchoconstrictive disorder. Therefore, the methods of both groups II and IV have the same mode of operation. As described in detail above, the methods of groups II and IV are related as a combination/subcombination for which a showing of two-way distinctness is required. The Office Action fails to provide such a showing.

Since such restriction is improper, reconsideration and withdrawal of the restriction requirement as between group II and group IV is, therefore, respectfully requested.

* * *

In view of the above, reconsideration and allowance of the application is respectfully requested.

Respectfully submitted,
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